

Remarks

Claims 1 to 41 and 85 to 92 are pending. Claims 1, 14-18, 27, and 85 are amended.

Applicants have corrected a typographical error on page 8 of the Specification.

§ 112 Rejections

Claims 1-41, and 85-92 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Patent Office asserts that it is unclear if an organic compound, complex or article (an agent) or if an agent that directs organic structure, is being claimed (claim 1). Claim 1 has been amended to make clear that Applicants' invention is directed to a particle comprising (a) an inorganic matrix comprising channels; (b) an organic structure-directing agent; and (c) an active agent; wherein the organic structure-directing agent and the active agent are disposed in the channels. (See, e.g., page 1, line 31 – page 2, line 1; and amended claim 1.)

The Patent Office also asserts that it is unclear what is intended by "structure directing." A structure-directing agent is an agent that, when in the presence of a condensable inorganic component, is capable of directing the structure that forms as the inorganic component condenses (page 6, lines 25-27). This means that the structure-directing agent provides a pattern around which the inorganic matrix condenses during formation of the controlled release particle (page 9, lines 14-16), thus patterning the channels of the inorganic matrix (page 9, lines 24-25). The pattern can be ordered (e.g., a template) or disordered (page 9, line 18), resulting in channels of a variety of configurations including, e.g., periodic arrays and random configurations (see page 9, lines 24-29). Useful organic structure-directing agents include surfactants and latex particles (see, e.g., page 11, line 1 – page 12, line 12, and amended claim 1).

The Patent Office also asserts that it is unclear what is intended by "controllably releasing", and by what means the particle would be capable of utilizing and how the particle, in what manner; would control release. Claims 1, 27, and 85 have been amended to render this objection mute.

The Patent Office also asserts that it is unclear what is intended by "associated" as to the metes and bounds of the claim limitation. Claim 13 is directed to a particle of the present

invention, wherein the active agent is “associated” with the organic structure-directing agent. A non-limiting example of such a composition is provided on page 13, lines 25-28, where a hydrophilic active agent can “associate with” the polar ends of a surfactant micelle (i.e., an organic structure-directing agent) such that the active agent is located on the exterior of the micelle.

Finally, the Patent Office asserts that the language “greater than about” is indefinite. Claims 14-18 have been amended to render this objection mute.

In summary, Applicants submit that the rejection of claims 1-41 and 85-92 under 35 USC § 112, second paragraph, has been overcome, and that the rejection should be withdrawn.

§ 102 Rejections

The present invention is directed to a particle comprising an inorganic matrix comprising channels; and a composition disposed in said channels, said composition comprising an organic structure-directing agent and an active agent. (See, e.g., page 1, line 31 – page 2, line 1; and amended claim 1.) The organic structure-directing agent, which comprises surfactant or latex particles, provides a pattern around which the inorganic matrix condenses during formation of the controlled release particle (page 9, lines 14-16), thus patterning the channels of the inorganic matrix (page 9, lines 24-25). The active agent is an agent that is capable of interacting with a biological system, a chemical system, or a combination thereof, when released from a particle. (See page 7, lines 1-3.)

Independent claims 1 and 27 stand rejected under 35 USC § 102(b) as being anticipated by Ducheyne et al. (US 5,591,453).

Ducheyne et al. teach the formation of bioactive glass using a sol-gel-derived process (col. 1, lines 10-14). Sol-gel synthesis of glasses is achieved by combining a metal alkoxide precursor, such as tetraethylorthosilane (TEOS) with water and an acid catalyst to produce a hydrolysis reaction with consequent polymerization of the metal alkoxide species and production of a gel (col. 5, lines 35-40).

According to the Patent Office, the organic structure-directing agent in Ducheyne et al. is either protons or water, or TMOS (tetramethylorthosilane). First, neither protons nor water constitute an organic material, thus Applicants respectfully submit that neither can be considered the organic structure directing agent of the present invention. Second, Ducheyne et al. disclose

sol-gel derived glass, formed by mixing TMOS (a silicon alkoxide precursor) combined with deionized water (col. 13, lines 16-25). The present invention teaches that alkoxysilanes (including, e.g., tetramethoxysilane and tetraethoxysilane) are useful condensable organic components (page 9, lines 8-16); however, the present invention also requires the presence of an organic-structure directing agent, which is present in the channels of the inorganic particle. Nothing in Ducheyne et al. teaches or suggests that the TMOS is an organic structure-directing agent, nor do Ducheyne et al. teach or suggest that any TMOS remains in the channels of the sol-gel derived glass.

For at least this reason, the rejection of independent claims 1 and 27 under 35 USC § 102(b) as being anticipated by Ducheyne et al. has been overcome and should be withdrawn.

Independent claims 1, 27, and 85 stand rejected under 35 USC § 102(b) as being anticipated by Constantz (US 6,005,162).

Constantz discloses the preparation of calcium phosphate minerals for physiological applications (col. 1, lines 21-24). Constantz teaches that a porous structure may be obtained by including water soluble materials which may be leached out, so as to provide for porosity in the mixture (col. 8, lines 1-3). Examples of such materials include, e.g., calcium carbonate, calcium sulfate, halite, and sugars (see col. 6, line 64 – col. 7, line 4), as well as soluble alkali metal salts such as calcium chloride and sodium or potassium hydroxide (see col. 8, lines 8-12). Porosity may also be achieved by the release of gas formed during the reaction to produce the product (col. 8, lines 3-5).

Constantz does not teach or suggest the use of surfactants of latex particles as organic structure-directing agents. Nor does Constantz teach or suggest channels containing both an organic structure-directing agent and an active agent.

The Patent Office also asserts that Constantz teaches the particle sizes of the present invention. However, the particle sizes disclosed by Constantz (col. 4, lines 9-16; and col. 5, lines 45-55) refer to the dry bulk powders before being formed into the final product. Nothing in Constantz teaches or suggests that these particles have channels, nor that they contain organic structure-directing agent or active agent.

For at least these reasons, the rejection of independent claims 1, 27, and 85 under 35 USC § 102(b) as being anticipated by Constantz has been overcome and should be withdrawn.

Independent claims 1, 27, and 85 stand rejected under 35 USC § 102(b) as being anticipated by Lee et al. (US 6,027,742).

Lee teaches bioresorbable ceramic compositions based on poorly crystalline apatitic (PCA) calcium phosphate combined with a suitable biocompatible matrix or additive (col. 7, lines 46-52). The composite materials of Lee are prepared by combining the PCA calcium phosphate with a selected supplementary material (col. 8, line 65 – col. 9, line 1). According to Lee, the supplementary material may be used as a particulate or liquid additive or doping material which is intimately mixed with the resorbable PCA calcium phosphate. It may serve as a matrix for the PCA calcium phosphate, which is embedded or dispersed within the matrix. Alternatively, the PCA calcium phosphate may serve as a matrix for the supplementary material which is dispersed therein. The supplementary material may be applied as a coating onto a PCA calcium phosphate body in a post-fabrication step. Lastly, the supplementary material may be coated with the PCA calcium phosphate. (See col. 9, lines 15-35.) Nothing in Lee teaches or suggests that the supplementary material is contained within channels formed in a PCA calcium phosphate particle.

Lee also teaches that a pharmaceutically active component may be added to the composite. Release of the agent occurs as the composite slowly degrades. (Col. 7, line 64 – Col. 8, line 2.) Again, however, nothing in Lee teaches or suggests that the agent is present in the channels of an inorganic matrix particle, rather, the agent is part of the composite itself.

For at least these reasons, the rejection of independent claims 1, 27, and 85 under 35 USC § 102(b) as being anticipated by Lee has been overcome and should be withdrawn.

Independent claim 1 stands rejected under 35 USC § 102(b) as being anticipated by Beck (US 5,057,296).

Beck teaches an improved method for synthesis of a novel synthetic composition of matter comprising ultra-large pore crystalline phase (col. 5, lines 3-6). The method of synthesis disclosed by Beck involves preparation of a particular reaction mixture comprising sources of alkali or alkaline earth metal cation, if desired, or a combination of oxides, and an organic directing agent. (See col. 10, lines 15-25.)

Nothing in Beck teaches or suggests that the organic directing agent remains in the pores after the product is formed. In fact, Beck teaches that the product should be dehydrated or calcinated at, for example, 540 °C for at least about one hour and other treatment if necessary, in

an attempt to remove any pore blocking contaminant (col. 9, lines 28-33). Lee also teaches thermal treatments at temperatures of 400 °C up to 750 °C (col. 9, lines 57-68).

Nor does Beck teach or suggest both an organic structure-directing agent and an active agent present in the channels. Beck teaches that the composition can be used as a catalyst component in intimate combination with a hydrogenating component. For example, aluminum may be present. (See col. 9, lines 36-56.) The Patent Office asserts that this aluminum is an active agent within the meaning of the present invention. However, nothing in Beck teaches or suggests that this aluminum is present in channels of an inorganic matrix. Rather, Beck teaches that the aluminum may be cocrystallized with the composition, exchanged into the composition, impregnated therein or intimately admixed therewith (col. 9, lines 45-50). Also, Beck teaches that when used as a catalyst, the composition should be subject to treatment to remove part or all of the organic component (col. 36-38). Thus, Beck teaches away from the present invention wherein both the organic structure-directing agent and the active agent are present in the channels of the final particle.

For at least these reasons, the rejection of independent claim 1 under 35 USC § 102(b) as being anticipated by Beck has been overcome and should be withdrawn.

§ 103 Rejections

Independent claims 1, 27, and 85 stand rejected under 35 USC § 103(a) as being unpatentable over Ducheyne et al. in view of Cataldo et al. (US 5, 856,271).

Ducheyne et al. has been discussed above.

Catadalo et al. teach a controlled release device that has fewer bubbles and voids (col. 6-7). Active chemical and carrier (e.g., carbon black) are blended in sufficient amounts to produce a bound friable mixture (col. 4, lines 56-67). The bound friable mixture is mixed with an amount of dispersible polymer to develop a homogenous dispersion of bound friable mixture in polymer powder (see col. 5, lines 39-49). Additional polymer powder is then added and the mixture may be formed by any plastic forming process (col. 5, lines 55 – 64). Thus, Catadalo et al. teaches devices comprising a polymeric matrix with inorganic material and active agent blended in the polymer. Nothing in Catadalo et al. teaches or suggests an organic structure-directing agent comprising surfactant or latex particles.

Because Cataldo et al. fail to address the deficiencies of Ducheyne et al., Applicants respectfully traverse the rejection of claims 1, 27, and 85 under § 103(a). Applicants respectfully submit that the Patent Office has failed to establish a prima facie case of obviousness, as the cited references in combination do not teach or suggest all the limitations of the claims.

The rejection of claims 1, 27, and 85 under 35 USC § 103(a) as being unpatentable over Ducheyne et al. in view of Cataldo et al. has been overcome and should be withdrawn.

Claims 2-26, and 29-41 each add additional features to claim 1. Claim 1 is patentable for the reasons given above. Thus, claims 2-26, and 29-41 are likewise be patentable.

Claims 28-38 each add additional features to claim 27. Claim 27 is patentable for the reasons given above. Thus, claims 28-38 are likewise be patentable.

Claims 86-92 each add additional features to claim 85. Claim 85 is patentable for the reasons given above. Thus, claims 86-92 are likewise be patentable.

In summary, the rejection of claims 1-41 and 85-92 under 35 USC §§ 102(b) and 103(a) as being unpatentable over Ducheyne et al., in view of Cataldo et al., has been overcome and should be withdrawn.

Restriction Requirement

In Applicants' previous response, Applicants elected Group I (claims 1-41 and 85-92) with traverse, to be prosecuted on the merits. The Patent Office noted that if Group IV was elected, Applicants would be required to select a patentably distinct species for prosecution on the merits. In response, the Patent Office made said election final and withdrew claims 42-84 and 93-108 from further consideration.

In the Office Action mailed December 18, 2002, the Patent Office submits that Applicants are required to elect a species of active agent, inorganic matrix, directing agent, and vehicle. Applicants respectfully traverse the Requirement for Restriction since the Patent Office has already conducted a search and rendered an Office Action on the merits in regard to claims 1-41, and 85-92. Applicants do not understand why an election of species is required after an Office Action on the merits or how such an election of species would aid the Patent Office in conducting a search, when presumably, a search has already been carried out. For these reasons, Applicants submit that the requirement for selection of species at this time is improper.

In the event the above election of species requirement is found to be proper, Applicants select the following species: active agent – trans 8, trans-10-dedecadien-1-ol (codlemone); inorganic matrix – silica; directing agent – surfactant; vehicle – water. Applicants believe that claims 1-5, 7, 8, 12-20, 22-24, 26-30, 35, 37, 38, 41, and 85-92 are readable thereon.

In view of the above, it is submitted that the application is in condition for allowance. Reconsideration of the application is requested.

Allowance of claims 1-41 and 85-92, as amended, at an early date is solicited.

Respectfully submitted,

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Date

By: 

Scott A. Bardell, Reg. No.: 39,594

Telephone No.: (651) 736-6935

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833

Version with markings to show amendments made:**In the Specification:**

On page 8, please replace the following paragraph starting on line 10 and ending on line 11:

Other useful methods of templating particles are described in, e.g., U.S. Patent No. 5,264,203 and WO [00/37705] 99/37705, and incorporated herein.

In the Claims:

1. (Amended) A particle comprising:
an inorganic matrix comprising channels; and
a composition disposed in said channels, said composition comprising an organic structure-directing agent and an active agent, **wherein the organic structure-directing agent comprises latex particles or surfactant**
[said particle being capable of controllably releasing said active agent].
14. (Amended) The particle of claim 1, wherein said particle has an average particle size of no greater than **[about]**20 um.
15. (Amended) The particle of claim 1, wherein said particle has an average particle size no greater than **[about]**15 um.
16. (Amended) The particle of claim 1, wherein said particle has an average particle size no greater than **[about]**1000 nm.
17. (Amended) The particle of claim 1, wherein said particle has an average particle size no greater than **[about]**100 nm.

18. (Amended) The particle of claim 1, wherein the channels of said particle have an average a cross-sectional dimension no greater than **[about]50 nm**.

27. (Amended) A first composition comprising:
a plurality of particles comprising
an inorganic matrix comprising channels; and
a second composition disposed in said channels, said second
composition comprising an organic structure-directing agent and an active
agent, **wherein the organic structure-directing agent comprises latex
particles or surfactant**
[said particles being capable of controllably releasing said active agent].

85. (Amended) A particle comprising:
an inorganic matrix comprising channels; and
a composition disposed in said channels, said composition comprising a
surfactant and an active agent selected from the group consisting of pharmaceutical
agents, therapeutic agents, antimicrobial agents, agricultural agents, curing agents, and
combinations thereof
[said particle being capable of controllably releasing the active agent].